

Paper No. 11. Of the remaining claims, Claim 1 is still the only independent claim.

Reconsideration and further examination are respectfully requested.

Withdrawn Claims 19 to 25 have been amended to retain consistency with Claims 1 to 18. As mentioned previously, and as acknowledged in the last Office Action, rejoinder of Claims 19 to 25 is requested upon an indication of allowance in Claims 1 to 18.

Claims 2 to 6 were objected to under 37 CFR 1.75(c), and Claims 1 to 18 were rejected under 35 U.S.C. § 112, second paragraph. This objection and rejection share a common premise: that Claim 2 was impermissibly broader than Claim 1. In response, Claim 2 has been amended to delete language that otherwise would have permitted a fragment of a Claim 1 sequence. Withdrawal of the objection and rejection is respectfully requested.

In addition, Claims 5, 7 and 9 to 13 were rejected based on allegedly unclear phraseology. These claims have been amended to improve clarity and withdrawal of the rejection is respectfully requested.

Claims 1 to 13 were rejected under 35 U.S.C. § 102 over Engel '779, Brennan '796 and Huisman. In entering these rejections, the Office Action took the position that Claims 1 to 18 actually covered fragments of the sequences of Claim 1, based on the language found in (unamended) Claim 2. In view of the amendment to Claim 2, which eliminates this reading, withdrawal of these § 102 rejections is respectfully requested.

Claims 1 to 13 were rejected under 35 U.S.C. § 103(a) over Huisman in view of Solaiman and Dieffenbach. Claims 1 to 18 were further rejected under 35 U.S.C.

§ 103(a) over Huisman in view of Doi '805. The grounds for rejection are respectfully traversed.

The presently claimed invention is directed to isolated nucleic acids consisting of (a) SEQ ID NOS. 1-9, (b) complementary base sequences of SEQ ID NOS. 1-9, (c) a mutation of (a) or (b) so long as the mutation is a modified sequence capable of hybridizing at 55°C with SEQ ID NOS. 1-9, and (d) complementary base sequences of (c).

Huisman merely describes PHA synthetase gene sequences derived from *P. oleovorans*. The Office Action conceded that “Huisman does not teach nucleic acids consisting of SEQ ID NO: 1-9. (page 11, paragraph 9, and page 14, paragraph 10).

Solainman discloses primers based on two highly conserved sequences of pseudomonad *phaC* genes. Dieffenbach teaches general concepts involved in primer design.

Doi discloses a probe with a base sequence of 5'-CC(G/C)CAGATCAACAAGTT(C/T)TA(C/G)GAC-3'.

Accordingly, none of the above, whether alone or together, disclose the presently claimed sequences.

In support of its rejections, the Office Action alleged that the presently claimed sequences are “functional equivalents” of the primers in Solainman and the probe in Doi, relying on *In re Deuel*, 34 USPQ2d 1210 (Fed. Cir. 1995). It is true that Deuel, in dicta, restates the general known proposition that structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. Even in this dicta, however, Deuel stresses the need for structure, whereas the Office

Action's mention of a "functional" equivalence underscores the inescapable fact that the cited art does not show structure relevant to the claims.

Indeed the Office Action's focus on this dicta of *In re Deuel* ignores its primary holding, which supports the patentability of the presently claimed sequences. In its holding, the U.S. Court of Appeals in *In re Deuel* affirmed that "the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs." (34 USPQ2d at 1215). The *In re Deuel* Court further elaborated that there must be "prior art that suggests the claimed compound in order for a *prima facie* case of obviousness to be made out." (34 USPQ2d at 1216). Consequently, the *In re Deuel* Court overruled the Board of Patent Appeals and Interferences for rejecting claims for isolated and purified DNA and cDNA molecules based upon alleged obviousness of a method of making the molecules because the the molecules were "specific compounds not suggested by the prior art." (34 USPQ2d at 1215).

In this instance, as explained above, Huisman does not teach or disclose the presently claimed sequences. Moreover, as Applicants understand Solainman and Doi, the present claimed sequences differ in structure from the primers in Solainman and the probe in Doi, since the base sequences of the presently claimed invention are not the same as the base sequences of the primers of Solainman and the probe in Doi. Dieffenbach only teaches methods or concepts to develop primers. Accordingly, none of the above prior art suggest or disclose the presently claimed sequences.

The Office Action further alleged that with methods known in Dieffenbach and in the art, it would have been obvious for one of ordinary skill in the art to develop or isolate primers and probes of the presently claimed sequences from the primers and probes disclosed in Solaiman and Doi. However, in *In re Deuel*, the U.S. Court of Appeals reversed the Board of Patent Appeals and Interference's rejection, noting that "[t]he PTO's focus on known methods for potentially isolating the claimed DNA molecules is also misplaced because the claims at issue define compounds, not methods." (34 USPQ2d at 1215). Likewise, in this case, the Office Action focuses on methods to isolate the presently claimed sequences as support for its § 103 rejections even though the rejected claims are directed to specific nucleotide sequences, and not methods for isolating or producing specific nucleotide sequences.

Additionally, the Office Action alleges that one of ordinary skill in the art would have been motivated to design alternative primers or probes of the present claimed sequences based on the entire gene sequence taught by Huisman. The Deuel Court addressed this position also, restating the O'Farrell rule that "obvious to try" has long been held not to constitute obviousness. (34 USPQ2d at 1216). As the *In re Deuel* Court pointed out, "the fact that one can conceive a general process in advance for preparing an *undefined* compound does not mean that a claimed *specific* compound was precisely envisioned and therefore obvious." (USPQ2d at 1216).

As demonstrated above, the Office Action's reliance on *In re Deuel* is misplaced. According to *In re Deuel*, in this instance, without envisioning their precise identity or structure, a general process or method of preparation does not render the presently claimed sequences obvious. The general concepts in Dieffenbach and the general

knowledge of designing probes in the art relate to potential processes for producing the presently claimed sequences. They do not add anything to the underlying lack of disclosure of the presently claimed nucleotide sequences. Therefore, Dieffenbach and the general knowledge of designing probes in the art do not remedy the deficiencies in Huisman, Solainman and Doi.

Consequently, none of the references, whether considered alone or in combination, discloses or suggests the present claimed invention nor renders it unpatentable.

Accordingly, it is respectfully requested that the claims be allowed and that the case be passed to issue.

Applicants' undersigned attorney may be reached in our Costa Mesa, California office at (714) 540-8700. All correspondence should continue to be directed to our below-listed address.

Respectfully submitted,


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APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE TO CLAIMS

2. (Twice Amended) A nucleic acid fragment that can be utilized as a primer or probe comprising the nucleic acid according to claim 1[, or a nucleic acid fragment comprising a partial sequence in a base sequence of the nucleic acid of claim 1].

5. (Twice Amended) A primer comprising a nucleic acid fragment that can be utilized as a primer according to any one of claims 2, 3 or 4, in which, as an additional modification, a marker [is attached to said nucleic acid fragment] and/or a moiety, which is attached to a solid-phase carrier, is bound to said nucleic acid fragment.

6. (Twice Amended) A probe comprising a nucleic acid fragment that can be utilized as a probe according to any one of claims 2, 3 or 4, in which, as an additional modification, a marker [is attached to said nucleic acid fragment] and/or a moiety, which is attached to a solid-phase carrier is bound to said nucleic acid fragment.

7. (Twice Amended) A primer comprising a combination of two different nucleic acid fragments with a substantial difference in their base sequences, wherein at least one of said two different nucleic acid fragments is a nucleic acid fragment for a primer according to claim 5[, and a marker, and/or a moiety attached to a solid-phase carrier, bound to each molecule

of said two nucleic acid fragments].

9. (Three Times Amended) The primer according to claim 7, wherein the base sequence of [said] at least one of said two different nucleic acid fragments is a modified base sequence subjected to a mutation, comprising partial deletion of the base sequence, addition of an extra base or base sequence, or substitution of a base or partial sequence in the base sequence with other base or base sequence, or a combination thereof, based on a base sequence shown in SEQ ID NO: 1 to 9 or complementary base sequence thereof.

10. (Three Times Amended) The primer according to claim 5, wherein said [primer comprises at least one kind of nucleic acid fragment subjected to an additional modification, and the additional modification in one kind of said nucleic acid fragment is a marker or a moiety bound to a solid-phase carrier, wherein said] marker or moiety is additionally bound to [a] the 5'-terminal side of the nucleic acid fragment.

11. (Three Times Amended) The probe according to claim 6, wherein said [probe comprises at least one kind of nucleic acid fragment subjected to an additional modification, and the additional modification in one kind of said nucleic acid fragment is a marker or a moiety bound to a solid-phase carrier, wherein said] marker or moiety is additionally bound to [a] the 5'-terminal side of the nucleic acid fragment.

12. (Three Times Amended) The primer according to claim 7, wherein said [primer comprises at least one different nucleic acid fragment subjected to an additional modification, and the additional modification in one different said nucleic acid fragment is a marker or a moiety bound to a solid-phase carrier, wherein said] marker or moiety is additionally bound to [a] the 5'-terminal side of the nucleic acid fragment.

13. (Three Times Amended) The primer according to claim 8, wherein said [primer comprises at least one kind of nucleic acid fragment subjected to an additional modification, and the additional modification in one kind of said nucleic acid fragment is a marker or a moiety bound to a solid-phase carrier, wherein said] marker or moiety is additionally bound to [a] the 5'-terminal side of the nucleic acid fragment.

19. (Amended) A method of detecting a PHA synthesizing microorganism, wherein said method uses at least one kind of nucleic acid fragment according to any one of claims 1 to 4 as a probe.

20. (Amended) A method of detecting a polyhydroxyalkanoate synthesizing microorganism, wherein said method uses at least one kind of nucleic acid fragment according to any one of claims 1 to 4 as a primer.